

## REMARKS

Enclosed is a copy of the claims of 09/000,604, 09/859,737 and PCT/US00/14621 which was requested by the Examiner. Also, enclosed are copies of Patent Nos. 5,898,244 & 5,990,379.

Claims 24, 36-39, 41-55, 74, 76-98, and 100-104, have also been rejected under 35 U.S.C § 112, second paragraph. Applicants again contend that the transitional phrase "consisting essentially of" is not confusing and indefinite and is in fact acceptable in form. See MPEP 2111.03. A biomaterial consisting essentially of tropoelastin can be produced using a crosslinking agent which is substantially dissipated during the formation of that biomaterial. Fibrin and polypeptides are not synonymous with tropoelastin and do not materially effect the structure of the biomaterial. Fibrin, polypeptides and crosslinking agents are clearly precluded by the language "consisting essentially of". The Examiner has offered no evidence to the contrary. The Examiner's position that fibrin, polypeptides and crosslinking agents are all material to the structure of the biomaterial is totally unsupported by any actual evidence. The Examiner's position is therefore traversed by the Applicants. The Examiner's view that the transitional phrase "consisting essentially of" should be interpreted as having the same scope as "comprising" is totally without foundation and is merely presumptive on his part.

Claims 1-10, 12, 13, 16-22, 24, 74, and 76-99 have been rejected under the judicially created doctrine of obviousness-type double patenting. A Terminal Disclaimer is provided herewith to overcome this rejection regarding any claims issuing in this application with respect to claims 1-10, 12-14, and 16-35 of U.S. Patent No. 6,087,552.

Claims 1-10, 13, 15-22, 24, 74, and 76-99 have been rejected under the judicially created doctrine of obviousness-type double patenting. A Terminal Disclaimer is provided herewith to overcome this rejection regarding any claims issuing in this application with respect to claims 1-10, 12-14, and 16-35 of U.S. Patent No. 6,110,212.

Claims 1-10, 13, 15-22, 24, 74, and 76-99 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting. Applicants have not filed a Terminal Disclaimer with respect to the claims of copending Patent Application 09/000,604 because no conflicting claims have been patented at this time.

Claims 101 and 102 have been indicated by the Examiner to be allowable if the rejection under 35 U.S.C § 112, second paragraph, were overcome. Applicants believe that this rejection has been overcome. Claim 101 has previously been rewritten in independent form, and claim 102 is dependent from claim 101.

Claims 1-13, 15-24, 36-55, 74, 76-100, and 103-104, have been rejected under 35 U.S.C. § 102(a) as being anticipated by Gregory et al, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Gregory et al in view of Labroo et al.

In order to have anticipation under 35 USC Section 102 (b), every element of the claim must be found in the prior art reference. As stated above, Gregory et al is not a valid reference.

The Examiner has found Applicants' Declaration under 37 C.F.R. 1.131 insufficient to overcome the rejections based on Gregory (WO 96/14807). Specifically, the Declaration was found lacking as to evidence of conception, due diligence, and the activities of co-inventor Barofsky.

The Examiner stated that applicants failed to show that they had full conception and appreciation of the present invention. It is believed that the Attorney for Applicants prepared the present application and was in contact with Applicants routinely from a date prior to May 23, 1996 to the present, and that Applicants disclosed to the Attorney for Applicants the subject matter of the present application on or before the publication of the Gregory (WO) reference.

It is therefore believed that these acts sufficiently demonstrate Applicants' full conception and appreciation of the presently claimed invention. "[T]he inventor's testimony must be sufficiently corroborated by independent evidence, but not necessarily documentary evidence." *Loral Fairchild Corp. v. Matsushita Electrical Industrial Co.*, 60 USPQ2d 1361, 1366 (Fed. Cir. 2001) (emphasis in original); see also MPEP 715.07 (independent evidence may be "attached supporting statements by witnesses, where verbal disclosures are the evidence relied upon.").

The Examiner further stated that no evidence was submitted to establish diligence from May 23, 1996 to February 7, 1997. Applicants assert that the exhibits to the Gregory Declaration contain evidence showing both engineering diligence and attorney diligence in preparation of the patent application. The evidence comprises the following dated entries in lab journals of inventors Andrew Barofsky (AB) and Kenton Gregory (KG):

- 5-23-96, AB book: under "Patent Ideas", remarks on "tropoelastin patent" (graft, stent covering, scaffolding uses);
- 5-28-96, KG book: "Patent work -- tropoelastin";
- 6-4-96, AB book: afternoon with JSM on "TPE patent";
- 6-24-96, KG book: notes "Patent Tropoelastin -- Andrew is working on";
- 7-11-96, AB book: states that "Jerry claims to have made progress adding stent stuff. . . should have a working final draft";
- 7-18-96, AB book: "TPE claims";
- 7-18-96, KG book: regarding "Tropo Patent", states that "Andrew to finish up on Marger most recent version";
- 10-15-96, AB book: "Jerry M. on vacation -- was going to work on final draft over weekend."; and
- 11-13-96, KG book: recites putting in "non-laser elastin applications claims" a list of things, including three "tropoelastin structure[s]" and several uses.

Before and during the critical period, the Attorney for Applicants believes that he was exposed to evidence demonstrating diligent effort in advancing the preparation of the present application, such as conversations regarding the invention, prior art and drafts of the claims and specification, and that therefore, Attorney for Applicants believes that conception occurred, and that attorney-diligence became relevant, on or about May 16, 1996 through to February 7, 1997.

Claims 47 and 48 have been rejected under 35 U.S.C. § 102 (b) as being anticipated by Bedell-Hogan et al. In order to have anticipation under 35 USC Section 102 (b), every element of the claim must be found in the prior art reference. Claims 47 and 48, as stated in prior response to this rejection, include the step of forming a biomaterial consisting essentially of tropoelastin. This is not described in the Bedell-Hogan et al reference. A discussion of the meaning of the transitional phase "consisting essentially of" is provided elsewhere in this response. Therefore, the above rejection does not constitute prima facie anticipation under 35 U.S.C. § 102 (b).

Claims 47, 48, and 53-55 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Labroo et al. In claims 47, 48, and 53-55, Applicants have added the language that the biomaterial employed is "consisting essentially of" tropoelastin. In order to have anticipation under 35 U.S.C. § 102(b), each and every element of the claim must be found in the prior art reference. Labroo et al relates to polypeptide materials. As stated in prior response to this rejection, Labroo et al does not disclose, suggest or teach a biomaterial consisting essentially of tropoelastin. A discussion of the meaning of the transitional phase "consisting essentially of" is provided elsewhere in this response. Therefore, the requirements for a prima facie case of anticipation have not been met with respect to the rejection of claims 47, 48, and 53-55 as being anticipated by the Labroo et al reference.

In light of the above arguments and amendments to the claims, it is requested that the Examiner reconsider his rejections and pass this case to issue. If, however, the Examiner still believes that has not responded to all of the rejections presently outstanding, he is encouraged to call the Attorney for the Applicants at the telephone number below to discuss same.



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Respectfully submitted,

A large, stylized handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

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## VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Second Amended) A method for producing a biomaterial fused onto a tissue substrate comprising:

providing a layer of said biomaterial consisting essentially of tropoelastin having a first and second outer major surface and a tissue substrate having a first and second outer major surface; and

applying an energy absorbing material, which is energy absorptive within a predetermined range of light wavelengths, to a selected one of said first and second outer surfaces of the biomaterial in an amount which will cause fusing together of one of said first and second outer surfaces of the biomaterial and one of said first and second outer surfaces of said tissue substrate, said energy absorbing material penetrating into the interstices of said biomaterial;

irradiating the energy absorbing material with light energy in said predetermined wavelength range with an intensity sufficient to fuse together one of said first and second outer surfaces of the biomaterial and the tissue substrate; and

fusing together the selected one of said first and second outer surfaces of the biomaterial and the tissue substrate.

23. (Third Amendment) A method for using a biomaterial as a tissue-fusible layer, comprising:

providing a layer of biomaterial consisting essentially of tropoelastin having a first and second outer major surface;

providing a tissue substrate having a first and second outer major surface; and

using [said] said biomaterial as a heat fusible material by applying an energy absorbing material, which is energy absorptive within a predetermined range of light wavelengths, to one of said first and second outer surfaces of the biomaterial in an amount which will make said biomaterial tissue-fusible, and which will cause fusing together of one of said first and second outer surfaces of the biomaterial and one of said first and second outer surfaces of said tissue substrate, said energy absorbing material being applied so that it will penetrate into the interstices of said biomaterial,

irradiating the energy absorbing material with light energy in said predetermined wavelength range with an intensity being sufficient to fuse together one of said first and second outer surfaces of the biomaterial and the tissue substrate.

47. (Fourth Amended) A method for producing a biomaterial, which comprises:  
providing a polymerizable monomer consisting essentially of tropoelastin;  
polymerizing said polymerizable monomer to form a polymer consisting essentially of tropoelastin; and  
forming [said] a biomaterial consisting essentially of tropoelastin from said polymer.

49. (Third Amended) The method of claim 100, which further includes the step of forming a three-dimensional support structure wherein said [material] biomaterial is combined with a stromal support matrix populated with actively growing stromal cells.

74. (Third Amended) A method for producing a biomaterial consisting essentially of tropoelastin joined to a tissue substrate comprising:

providing a layer of said biomaterial consisting essentially of tropoelastin having a first and second outer major surface; and

applying an energy absorbing material, which is energy absorptive within a predetermined range of light wavelengths, to a selected one of said first and second outer surfaces of the biomaterial in an amount which will cause fusing together of one of said first and second outer surfaces of the biomaterial and an outer surface of said tissue substrate, said energy absorbing material penetrating into the interstices of said biomaterial,

the selected one of said first and second outer surfaces of the biomaterial being capable of joining together with the outer surface of the tissue substrate by irradiating the energy absorbing material with light energy in a predetermined wavelength range with an intensity sufficient to facilitate said joining together of said biomaterial and said tissue substrate.

89. (Amended) The method of claim 76, wherein [so that] the tissue substrate is a live tissue substrate.

91. (Twice Amended) The method of claim 76, which further includes the step of forming [an into] a three-dimensional support structure wherein said [material] biomaterial is combined with a stromal support matrix populated with actively growing stromal cells.

99. (Thrice Amended) A method for producing an biomaterial fused onto a tissue substrate comprising:

providing a biomaterial layer consisting essentially of [biomaterial] tropoelastin having a first and second outer major surface and a tissue substrate having a first and second outer major surface;

applying an energy absorbing material, which is energy absorptive within a predetermined range of light wavelengths, to one of said first and second outer surfaces of the biomaterial in an amount which will cause fusing together of one of said first and second outer surfaces of the biomaterial and one of said outer surface of said tissue substrate, said energy absorbing material penetrating into the interstices of said biomaterial;

indirectly irradiating the energy absorbing material by directing the light energy first through the biomaterial or tissue substrate and then to the energy absorbing material, said light energy being in said predetermined wavelength range with an intensity sufficient to fuse together one of said first and second outer surfaces of the crosslinked biomaterial and the outer surface of said tissue substrate; and

fusing together one of said first and second outer surfaces of the crosslinked biomaterial and the outer surface of said tissue substrate and substantially dissipating said energy absorbing material when said crosslinked biomaterial and said tissue substrate are fused together.

101. (Amended) A method for producing a [tropoelastin] biomaterial, which comprises: providing a monomer consisting essentially of tropoelastin;

polymerizing said [tropoelastic] monomer to form a polymer consisting essentially of tropoelastin;

forming a biocompatible [tropoelastin] biomaterial consisting essentially of tropoelastin from said [tropoelastin] polymer; and

forming a three-dimensional support structure wherein said [tropoelastin] biomaterial is combined with a stromal support matrix populated with actively growing stromal cells.

103. (Twice Amended) A method for producing a [tropoelastin] biomaterial, which comprises:

providing a monomer consisting essentially of tropoelastin;

polymerizing said [tropoelastic] monomer to form a polymer consisting essentially of tropoelastin;

forming a [tropoelastin] biomaterial from said [tropoelastin] polymer; and

forming a cellular lining of human cells on one of the major surfaces of said [tropoelastin] biomaterial.